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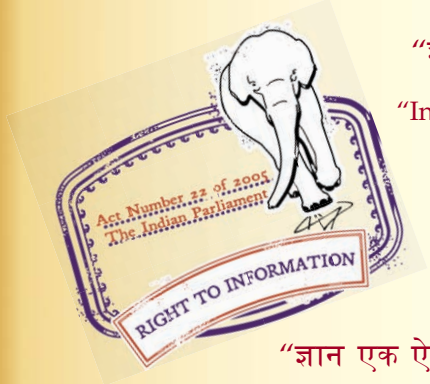
IS 3237-1 (1985): Special Purpose Syringes, Part 1: Insulin Syringes [MHD 12: Hospital Equipment]



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"Knowledge is such a treasure which cannot be stolen"

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Indian Standard (Reaffirmed 2006)

SPECIFICATION FOR SPECIAL PURPOSE SYRINGES

PART 1 INSULIN SYRINGES

(Second Revision)

Medical Glass Instruments and Appliances Sectional Committee, CPDC 12 ; Hypodermic Syringes Subcommittee, CPDC 12 : 1, [Ref : Doc : CPDC 12 (1771)]

1. Scope — Covers requirements for insulin syringes.

1.1 Unless otherwise stated in this standard, the provisions stipulated in IS : 3235 - 1980 'General requirements for syringes for medical use (*first revision*)' shall apply.

2. Types, Shape, Capacity and Dimensions

Long type insulin syringe — 0·5, 1 and 2 ml capacity.

Short type insulin syringe — 1 and 2 ml capacity.

2.2 The syringe shall be of all glass type. Typical shape for long type syringe is shown in Fig. 1. Short type syringe shall be as shown in Fig. 1A of IS : 3236 - 1980 'Specification for hypodermic syringes for general purposes (*first revision*)'.

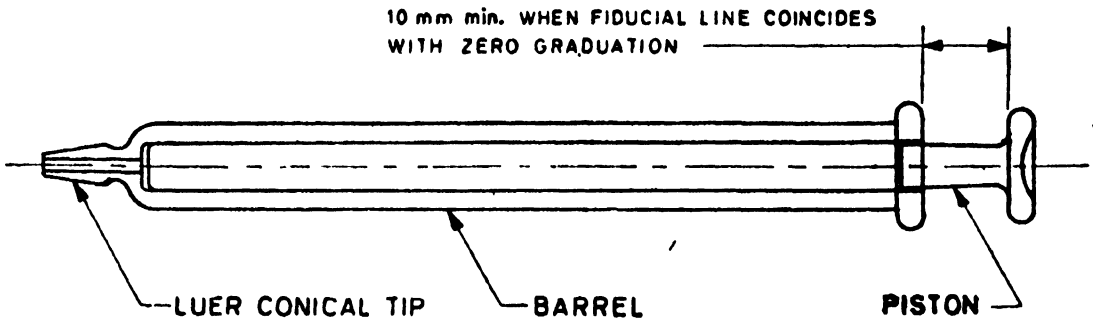

FIG. 1 INSULIN SYRINGE

2.3 The graduations for both types are as given below :

Long Type

a) 0·5 ml capacity syringe shall have graduation of 0·1 ml,

b) 1 ml capacity syringe shall have graduation of 0·1 ml, or
1 ml capacity syringe shall have graduation of 40 units of U - 40 in 1 unit divisions, and

c) 2 ml capacity syringe shall have graduation of 80 units of U - 40 in 2 unit division.

Short Type

a) 1 ml capacity syringe shall have graduation of 40 unit of U - 40 in 1 unit divisions,

b) 2 ml capacity syringe shall have graduation of 80 units of U - 40 in 2 unit divisions.

2.3.1 The syringe of 1 ml capacity having scale of 40 units and syringe of 2 ml capacity having scale of 80 units shall be marked with the words U - 40 near the graduation scale.

2.3.2 No double graduations are permitted to be marked on the same syringe.

2.4 The capacities, scale intervals and other critical dimensions of the syringes shall be in accordance with Table 1. The length of barrel shall be such as to allow at least 25 percent more liquid than the full capacity marked on the barrel.

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TABLE 1 CAPACITIES, AND CRITICAL DIMENSIONS OF INSULIN SYRINGE

(*Clause* 2.4)

Type	Graduated Capacity of Syringes ml	Tolerance on Graduated Capacity Percent	Maximum Overall Length mm	Minimum Length of Scale mm	Scale Intervals	Numbering of Scale Intervals	Minimum Thickness of Glass mm	Effluent Diameter mm
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Long	0·5	± 5	90	31	0·1 ml	0·1, 0·2, 0·3, ·4 and ·5	1·0	0·8 to 1·2
Long	1	± 5	115	50	0·1 ml	0·1, 0·2, 0·3 0·4, 0·5, 0·6, 0·7, 0·8, 0·9 and 1	1·2	0·8 to 1·6
Long	1	± 5	115	50	1 unit	10, 20, 30, 40	1·2	0·8 to 1·6
Long	2	± 5	125	58	2 unit	20, 40, 60, 80	1·2	0·8 to 1·6
Short	1	± 5	85	25	1 unit	10, 20, 30, 40	1·0	0·8 to 1·6
Short	2	± 5	100	27	2 unit	20, 40, 60, 80	1·2	0·8 to 1·6

3. Requirements

3.1 *Nozzle* — The male conical tip of nozzle shall be Luer or Luer lock type and shall comply with IS : 3234 - 1979 'Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (*first revision*)'. The Luer lock connection shall be in accordance with Fig. 2 of IS : 3236 - 1980 'Specification for hypodermic syringes for general purposes (*first revision*)' till the publication of the second revision of IS : 3234.

3.2 *Graduation and Numbering* — The numbering of scale intervals shall be in accordance with Table 1. The number shall be close to but shall not touch the ends of the graduation mark to which it relates. The numbering shall generally conform to the details given in Fig. 2.

3.3 *Piston*

3.3.1 The piston shall be white or blue glass. It shall be easily visible through the barrel and the fiducial line shall be capable of being judged against the graduation very accurately.

3.4 The effluent diameter shall be in accordance with Table 1, and it shall be concentric with tip. The tip shall be ground to suit the hub of the needle.

4. Tests

4.1 All tests provided under 8 of IS : 3235 - 1980 shall be applicable.

4.2 Leakage test as described in 8.8 of IS : 3235 - 1980 for 0·5 ml syringe shall be done by applying pressure of 250 kN/m^2.

5. Marking — Each syringe shall be legibly and indelibly marked with the following:

a) Capacity and graduations as specified in Table 1 and Fig. 2;

b) Means of identification of barrel and piston;

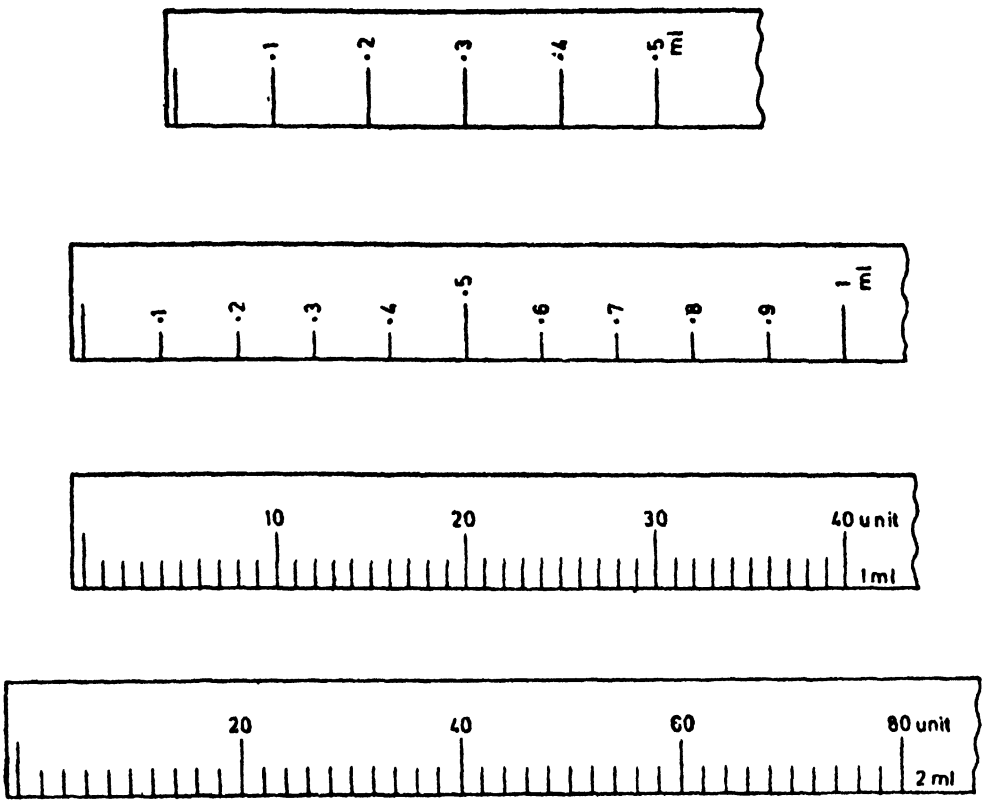
c) Manufacturer's name, initials or recognized trade-mark; and

d) Word 'Insulin'.

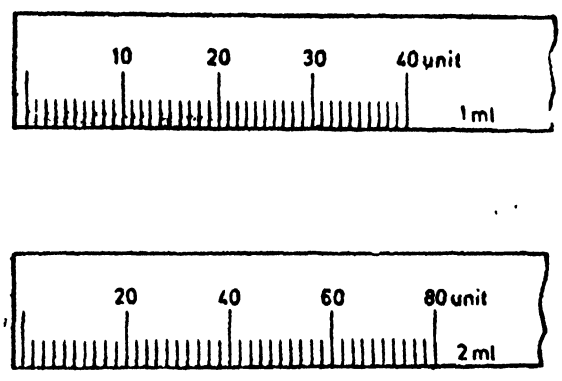
5.1 *ISI Certification Marking* — Details available with the Indian Standards Institution.

6. Packing — Each syringe shall be wrapped in cotton wool and packed in a cardboard carton. Alternatively, the packing may be done as agreed to between the purchaser and the supplier.

7. Sampling — Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However a recommended sampling plan is given in Appendix A.



LONG TYPE



SHORT TYPE

FIG. 2 GRADUATION OF INSULIN SYRINGE

APPENDIX A

(*Clause* 7)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1. Lot

A-1.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimension under similar conditions shall constitute a lot.

A-1.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

TABLE 2 SCALE OF SAMPLING

Lot Size (1)	Sample Size (2)	Sub-Sample Size (3)
Up to 100	5	5
101 „ 150	8	5
151 „ 500	13	8
501 „ 1 000	20	13
1 001 „ 10 000	32	13
10 001 and above	50	20

A-1.2.1 These syringes shall be selected from the lot at random and in order to ensure the randomness of selection procedures given in IS : 4905 - 1968 'Methods for random sampling' may be followed.

A-2. Number of Tests and Criteria For Conformity

A-2.1 All the syringes selected at random in accordance with col 1 and 2 of Table 1 shall be tested for dimensions, capacity, shock test, leakage test, test for entraped fluid and freedom from straie and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.

A-2.2 If the lot is found to be conforming to the requirements given in **A-2.1**, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 2. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.

A-2.3 The lot shall be considered as conforming to the standard if **A-2.1** and **A-2.2** are satisfied.

EXPLANATORY NOTE

This standard has been splitted into several parts in second revision. The following parts have been published while the others are under formulation:

Part 2 Tuberculine syringes

Part 3 BCG syringes

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